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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,839	03/01/2001	John R. White	P 50836	6619

20462 7590 10/18/2002

SMITHKLINE BEECHAM CORPORATION
CORPORATE INTELLECTUAL PROPERTY-US, UW2220
P. O. BOX 1539
KING OF PRUSSIA, PA 19406-0939

EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 10/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/786,839

Applicant(s)

WHITE, JOHN R.

Examiner

Cybille Delacroix-Muirheid

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The following is responsive to Applicant's remarks and declaration received July 30, 2002.

No claims are cancelled. No new claims are added. Claims 1-6 are currently pending.

1. Upon further review and consideration of Applicant's declaration received Jan. 23, 2002, it has been discovered that the declaration is technically flawed because it does not contain an allegation that the acts relied upon to establish the date prior to the reference were carried out on this country or in a NAFTA country or WTO member country. Please see MPEP 715.07(c).

Therefore, the declaration was not sufficient to overcome the White et al. reference.

Consequently, the previous 35 USC 103(a) rejection is reinstated and set forth at paragraphs 7-9 below.

2. The declaration filed on July 30, 2002 under 37 CFR 1.131 has been considered but is ineffective to overcome the Widdowson reference (WO 97/49400). The declaration is technically flawed because it does not contain an allegation that the acts relied upon to establish the date prior to the reference were carried out on this country or in a NAFTA country or WTO member country. Please see MPEP 715.07(c).

3. Accordingly, the previous rejection under 35 USC 103(a) set forth in paragraphs 4-6 of the office action mailed April 23, 2002 is maintained.

4. In the response received Jul. 30, 2002, Applicant's arguments regarding the previous rejection under 35 USC 102(b), set forth in paragraphs 2-3 of the office action mailed April 23, 2002 have been considered and found persuasive. However, because the declaration under 37

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CFR 1.131 is technically flawed and therefore ineffective to overcome the Widdowson reference, the following new ground of rejection is submitted:

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 1, 4 are rejected under 35 U.S.C. 102(a) as being anticipated by Widdowson WO 97/49400.

Widdowson discloses that CXCR2 (IL-8 β receptor, type II IL-8 receptors) compounds of Formula I inhibit chemotaxis of neutrophils and that said compounds may be useful in treating a variety of diseases in a mammal such as psoriasis, asthma, arthritis, inflammatory diseases, etc. Please see page 20, lines 1-29; page 22, lines 1-7; page 25, lines 31-35.

The claims are anticipated by Widdowson because Widdowson discloses administration of identical agents, i.e CXCR2 inhibitors, to a host using Applicant's method steps. Accordingly, inhibition of T-cell mediated and neutrophil chemotaxis is inherent.

Claim Rejections - 35 USC § 103

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7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over White et al. in view of Widdowson.

White et al. teach methods of administering the CXCR2 antagonist (N-(2-hydroxy-4-nitrophenyl)-N-(2-bromophenyl)urea) to rabbits. Results demonstrate that said antagonist inhibited IL-8 induced neutrophil migration. Please see the abstract.

White does not disclose administration of the CXCR2 antagonist to humans or that the antagonist inhibits T-cell chemotaxis. However, the Examiner refers to Widdowson which discloses that CXCR2 compounds inhibit chemotaxis of neutrophils and T-cells and further that

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said compounds may be useful in treating a variety of diseases such as psoriasis or asthma.

Please see the abstract.

It would have been obvious to one of ordinary skill in the art to modify the method of White to administer the antagonists to humans, as taught by Widdowson, because Widdowson raises reasonable expectation of success by disclosing that CXCR2 compounds are effective in inhibiting neutrophil and T-cell chemotaxis in humans. Thus, such a modification would have been motivated by the reasoned expectation of successfully treating humans in need of inhibition of neutrophil or T-cell chemotaxis.

With respect to further administering CXCR1 compounds, this would have been obvious to one of ordinary skill in the art in view of White which discloses that the CXCR1 receptor is also involved in the activation of neutrophils through IL-8 (see abstract). One of ordinary skill in the art would reasonably expect antagonists of CXCR1 to also inhibit the migration of neutrophils.

Conclusion

Claims 1-6 are rejected.

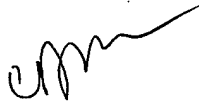
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

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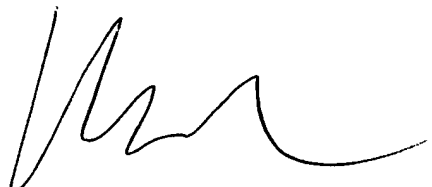
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CDM



Oct. 17, 2002



MARIANNE C. SEIDEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600